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Understanding and Using the New *2020-2025 Dietary Guidelines for Americans*

**Webinar 3: Designing, Implementing, and Presenting Research to be
Reviewed by the 2025 Dietary Guidelines Advisory Committee**

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Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	None
Scientific Advisory Board/Consultant/Board of Directors	California Walnut Commission Health Research Advisory Group
Speakers Bureau	Academy of Nutrition & Dietetics Vegetarian Nutrition National Speakers Bureau
Stock Shareholder	None
Employee	Nutrition On Demand
Other	Adjunct Faculty, George Washington University

Learning Objectives

At the end of this program, attendees will be able to:

- Describe the robust, seven-step NESR approach which supported the 2020 Dietary Guidelines Advisory Committee in conducting systematic reviews on topics relevant to Federal policy and programs
- Utilize the NESR methodology as a guide when designing research studies and publishing study findings

CPE Credit

- ASN designates this educational activity for a maximum of 1 CPEUs. Dietitians and Dietetic Technicians, Registered should only claim credit commensurate with the extent of their participation in the activity.
- To claim credit, please take the post webinar evaluation provided after the webinar.

Asking Questions

- Please use the “questions” box on your “Go To Meetings” screen to submit questions to our presenters.
- Please submit your questions at any time during today’s webinar.

Nutrition Evidence Systematic Review (NESR) Methodology

Julie E. Obbagy, PhD, RDN



Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	None
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Stock Shareholder	None
Employee	U.S. Department of Agriculture
Other	None

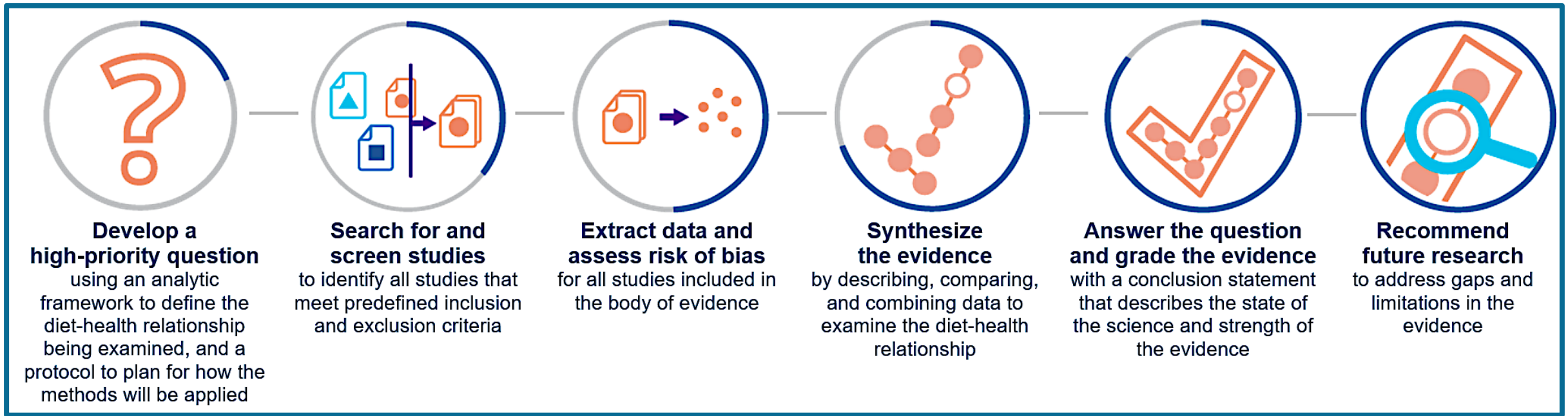
NESR supported the 2020 Dietary Guidelines Advisory Committee's systematic reviews



NESR Systematic Review

Research project that answers a question on diet and health by searching for, evaluating, and synthesizing all relevant, peer-reviewed studies.

For more information on NESR visit: <https://nesr.usda.gov/>



The Committee and NESR conducted systematic reviews in a collaborative manner

The 2020 Advisory Committee:

- ✓ Established all aspects of the protocol (i.e., the plan for how the Committee would examine the scientific evidence), including the inclusion and exclusion criteria
- ✓ Reviewed all studies that meet the criteria they set
- ✓ Deliberated on the body of evidence for each question
- ✓ Wrote and graded the conclusion statements to be included in the scientific report the 2020 Committee submitted to USDA and HHS

NESR Staff:

Supported the Advisory Committee by facilitating, executing, and documenting the work necessary to ensure the reviews are done in accordance with NESR methodology



NESR's team of scientists who supported the 2020 Committee



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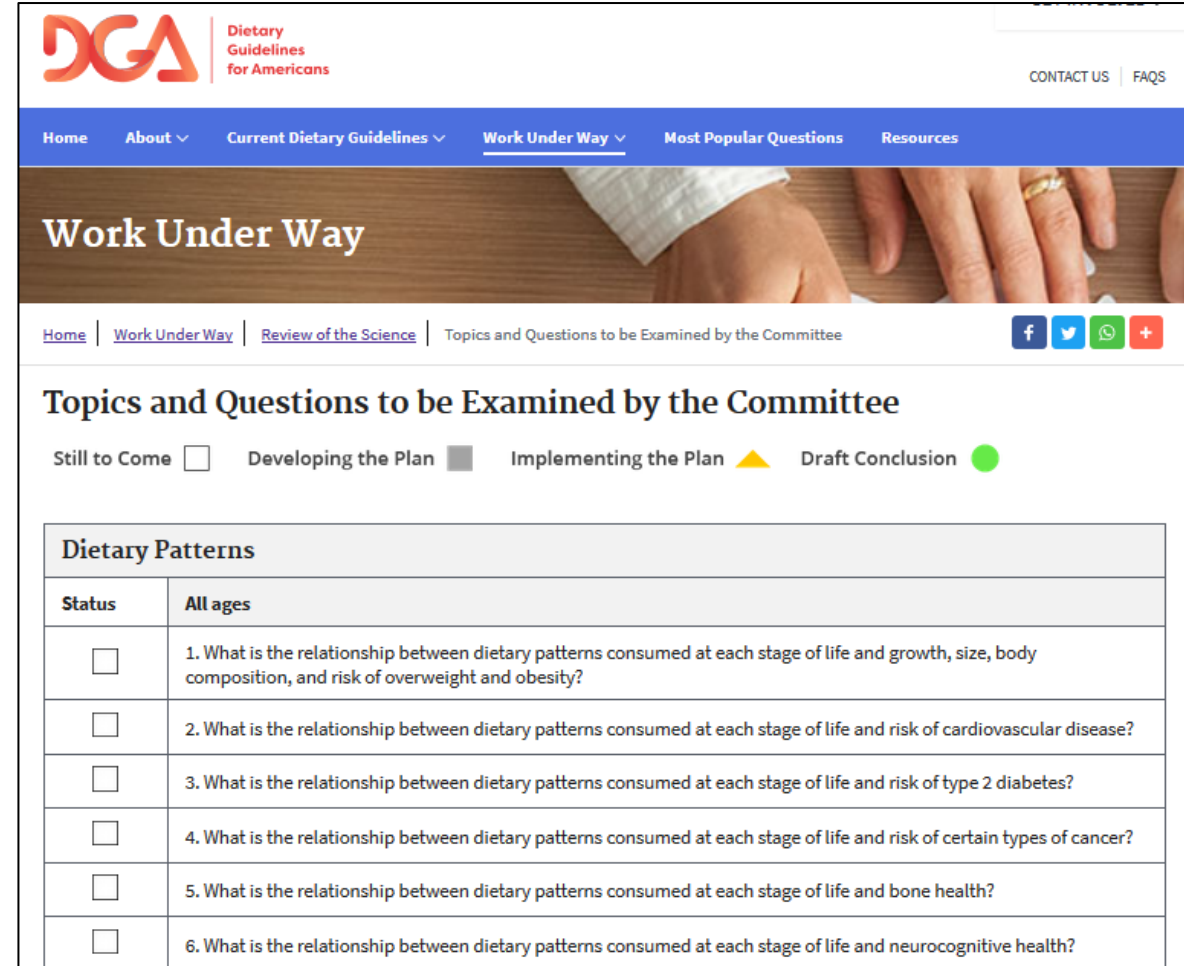


Nancy Terry,
MLS

A protocol was developed for each systematic review question

A systematic review protocol is the plan for how a specific systematic review will be conducted and includes:

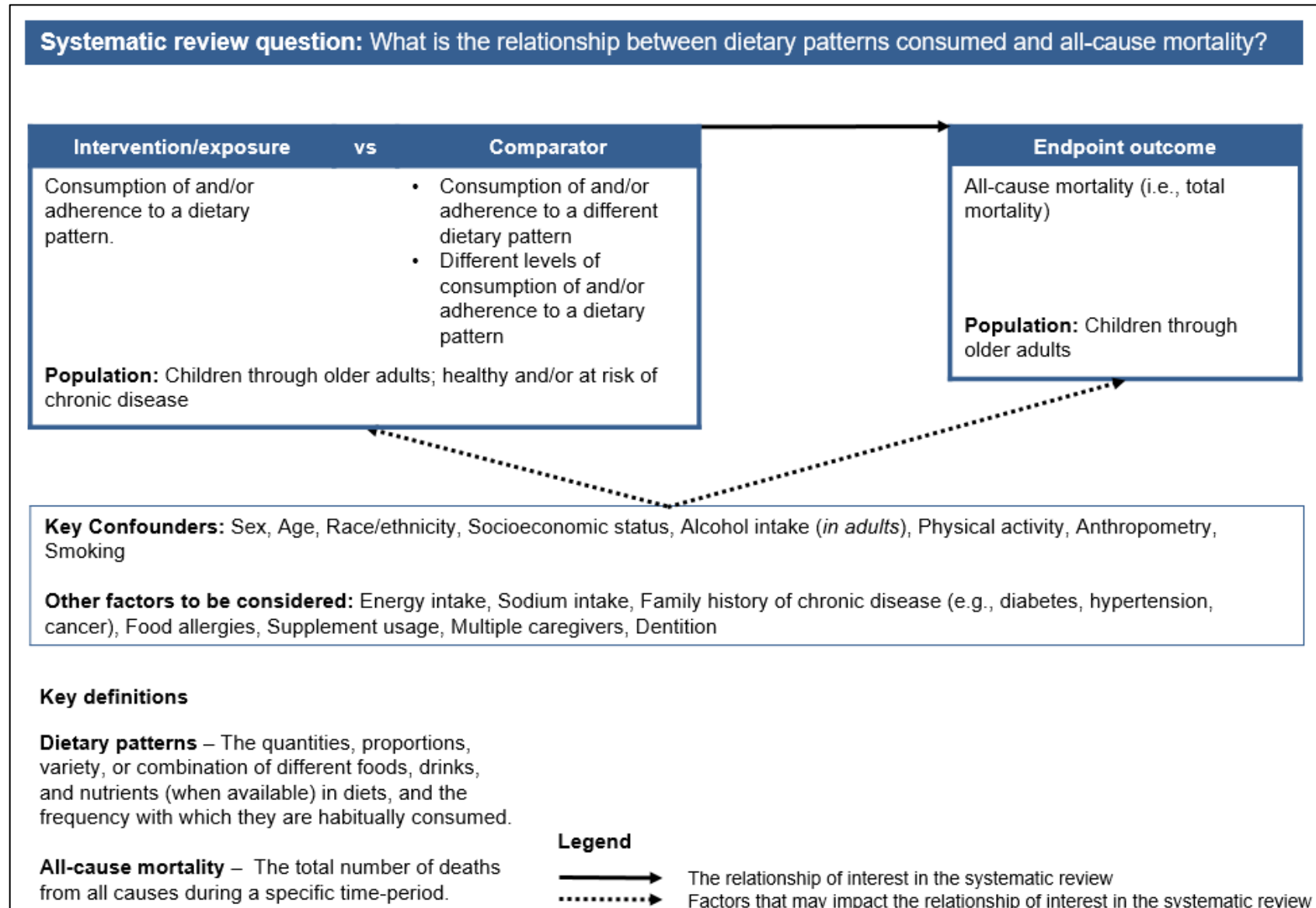
- Analytic framework
- Inclusion and exclusion criteria
- Search strategy
- Flow chart of literature search and screening results
- Lists of included and excluded articles



The screenshot shows the 'Dietary Guidelines for Americans' website. The main navigation bar includes 'Home', 'About', 'Current Dietary Guidelines', 'Work Under Way', 'Most Popular Questions', and 'Resources'. The 'Work Under Way' section is highlighted, showing a list of 'Topics and Questions to be Examined by the Committee'. The topics are categorized by status: 'Still to Come' (white square), 'Developing the Plan' (grey square), 'Implementing the Plan' (yellow triangle), and 'Draft Conclusion' (green circle). The table below lists six dietary patterns under the 'All ages' category, all of which are currently 'Still to Come'.

Dietary Patterns	
Status	All ages
☐	1. What is the relationship between dietary patterns consumed at each stage of life and growth, size, body composition, and risk of overweight and obesity?
☐	2. What is the relationship between dietary patterns consumed at each stage of life and risk of cardiovascular disease?
☐	3. What is the relationship between dietary patterns consumed at each stage of life and risk of type 2 diabetes?
☐	4. What is the relationship between dietary patterns consumed at each stage of life and risk of certain types of cancer?
☐	5. What is the relationship between dietary patterns consumed at each stage of life and bone health?
☐	6. What is the relationship between dietary patterns consumed at each stage of life and neurocognitive health?

The analytic framework defined core elements of the systematic review question



Inclusion and exclusion criteria were established, up front

Category	Inclusion Criteria	Exclusion Criteria
Study design	• Randomized controlled trials • Non-randomized controlled trials, including quasi-experimental and controlled before and after studies • Prospective cohort studies • Retrospective cohort studies • Nested case-control studies	• Uncontrolled trials • Case-control studies • Cross-sectional studies • Uncontrolled before-and-after studies • Narrative reviews • Systematic reviews • Meta-analyses
Intervention/exposure	Consumption of and/or adherence to a dietary pattern [i.e., the quantities, proportions, variety, or combination of different foods, drinks, and nutrients (when available) in diets, and the frequency with which they are habitually consumed], including, at a minimum, a description of the foods and beverages in the pattern → Dietary patterns may be measured or derived using a variety of approaches, such as adherence to a priori patterns (indices/scores), data driven patterns (factor or cluster analysis), reduced rank regression, or other methods, including clinical trials	No description of the dietary pattern, which at minimum, must include the foods and beverages in the pattern (i.e., studies that examine a labeled dietary pattern, but do not describe the foods and beverages consumed)
Comparator	• Consumption of and/or adherence to a different dietary pattern • Different levels of consumption of and/or adherence to a dietary pattern	N/A

Inclusion and exclusion criteria, continued...

Category	Inclusion Criteria	Exclusion Criteria
Outcomes	All-cause mortality (i.e., total mortality): the total number of deaths from all causes during a specific time-period	Studies that only report cause-specific mortality
Date of publication	January 2000 – May 2019	Articles published prior to January 2000 or after May 2019
Publication status	Articles that have been peer-reviewed	Articles not peer-reviewed or not published in peer-reviewed journals, including unpublished data, manuscripts, pre-prints, reports, abstracts, and conference proceedings
Language of publication	Articles published in English	Articles published in languages other than English
Country	Studies conducted in countries ranked as high or higher human development	Studies conducted in countries ranked as medium or lower human development

Inclusion and exclusion criteria, continued...

Category	Inclusion Criteria	Exclusion Criteria
Study participants	Human participants, males and females	Non-human participants (i.e., animals); Women during pregnancy and lactation
Age of study participants (at intervention or exposure, outcome)	Children and adolescents, adults, and older adults (ages 2 years and above)	Infants and toddlers (birth to 24 months)
Health status of study participants	• Studies that enroll participants who are healthy and/or at risk for chronic disease, including those with obesity • Studies that enroll some participants diagnosed with a disease	• Studies that exclusively enroll participants diagnosed with a disease or hospitalized with illness or injury. (For this criterion, studies that exclusively enroll subjects with obesity were included.)

A literature search was conducted to find *all* relevant studies

NESR Librarians

→ created *literature*
→ peer reviewed *search*
→ executed *strategies*

in

- PubMed
- Embase
- Cochrane Central Register of Controlled Trials (CENTRAL)

PubMed

Provider: U.S. National Library of Medicine

Date(s) Searched: October 4, 2019

Date range searched: January 1, 2000-October 4, 2019

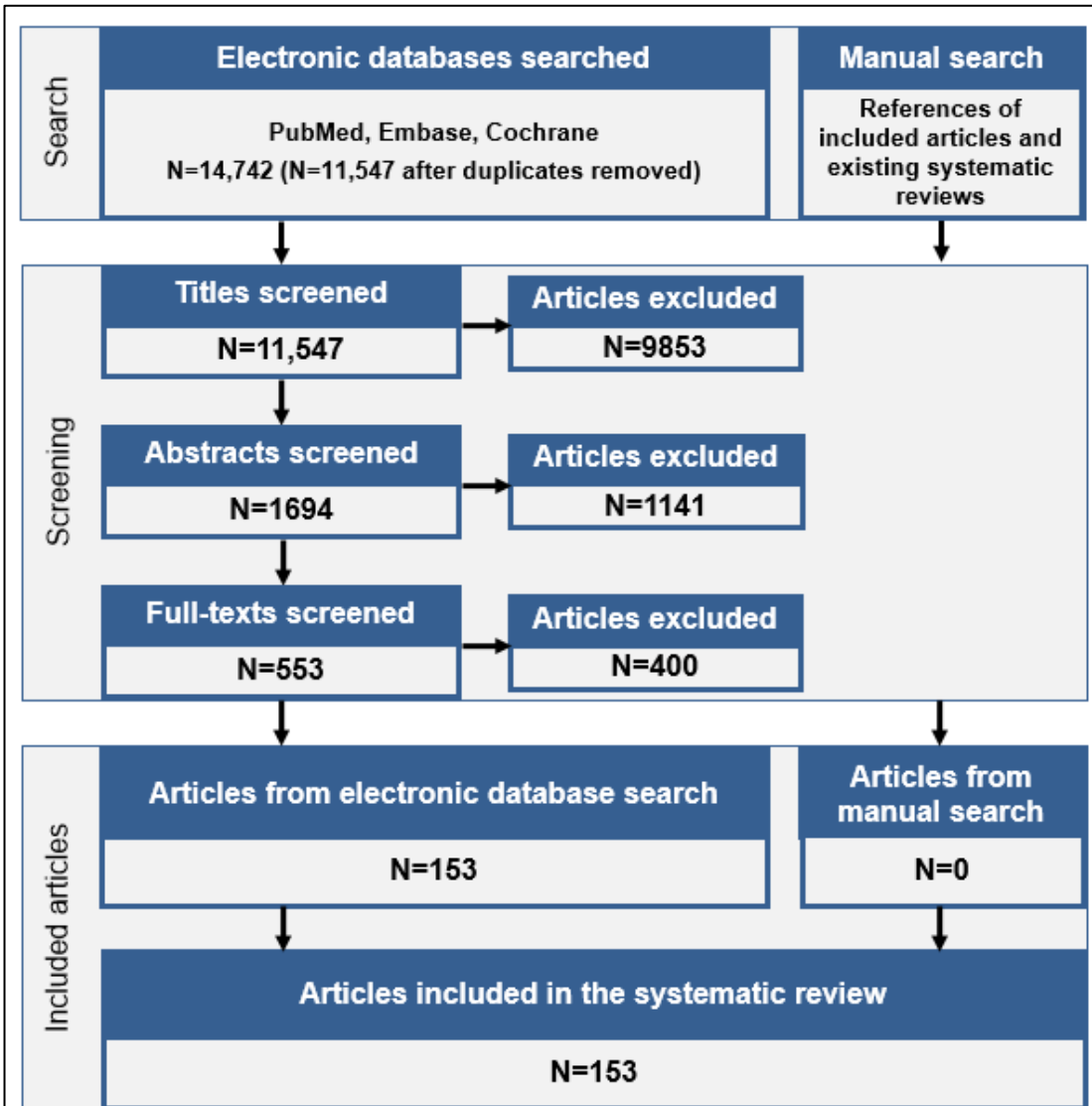
#1 - dietary pattern* OR diet pattern* OR eating pattern* OR food pattern* OR diet quality* OR eating habit* OR dietary habit* OR diet habit* OR food habit* OR beverage habit* OR "Feeding Behavior"[Mesh:NoExp] OR dietary profile* OR food profile* OR diet profile* OR eating profile* OR dietary guideline* OR dietary recommendation* OR dietary intake* OR eating style* OR "Diet, Mediterranean"[Mesh] OR Mediterranean Diet*[tiab] OR "Dietary Approaches To Stop Hypertension"[Mesh] OR Dietary Approaches To Stop Hypertension Diet* OR DASH diet* OR "Diet, Gluten-Free"[Mesh] OR Gluten Free diet* OR prudent diet* OR "Diet, Paleolithic"[Mesh] OR Paleolithic Diet* OR "Diet, Vegetarian"[Mesh] OR vegetarian diet*[tiab] OR vegan diet* OR "Diet, Healthy"[Mesh] OR plant based diet* OR "Diet, Western"[Mesh] OR western diet* OR "Diet, Carbohydrate-Restricted"[Mesh] OR low-carbohydrate diet* OR high carbohydrate diet* OR Ketogenic Diet* OR Nordic Diet* OR "Diet, Fat-Restricted"[Mesh] OR "Diet, High-Fat"[Mesh] OR "Diet, High-Protein"[Mesh] OR high protein diet*[tiab] OR protein intake* OR high-fat diet* OR low fat diet* OR "Diet, Protein-Restricted"[Mesh] OR low protein diet* OR "Diet, Sodium-Restricted"[Mesh] OR low-sodium diet* OR low salt diet* OR (("Dietary Proteins"[Mesh] OR dietary protein*[tiab] OR "Dietary Carbohydrates"[Mesh] OR dietary carbohydrate*[tiab] OR "Dietary Fats"[Mesh] OR dietary fat*[tiab] OR hypocaloric OR hypo-caloric) AND (diet[tiab] OR diets[tiab] OR consumption[tiab] OR intake[tiab] OR supplement*[tiab])) OR (("Guideline Adherence"[Mesh] OR guideline adherence*) AND (diet[tiab] OR dietary[tiab] OR food[tiab] OR beverage*[tiab] OR nutrition*[tiab])) OR diet score* OR diet quality score* OR diet quality index* OR kidmed OR diet index* OR dietary index* OR food score* OR MedDietScore OR healthy eating index[tiab] OR ((pattern[tiab] OR patterns[tiab] OR consumption[tiab] OR habit*[tiab]) AND ("Diet"[Mesh:NoExp] OR diet[tiab] OR diets[tiab] OR dietary[tiab] OR "Food"[Mesh] OR food[tiab] OR foods[tiab] OR "Beverages"[Mesh] OR beverage[tiab] OR beverages[tiab]))

#2 - "Mortality"[Mesh] OR "mortality" [Subheading] OR mortality [tiab]

#3 - (#1 AND #2)

#4 - (#1 AND #2) NOT ("Animals"[Mesh] NOT ("Animals"[Mesh] AND "Humans"[Mesh])) NOT (editorial[ptyp] OR comment[ptyp] OR news[ptyp] OR letter[ptyp] OR review[ptyp] OR systematic review[ptyp] OR systematic review[ti] OR meta-analysis[ptyp] OR meta-analysis[ti] OR meta-analyses[ti] OR retracted publication[ptyp] OR retraction of publication[ptyp] OR retraction of publication[tiab] OR retraction notice[ti]) Filters: Publication date from 2000/01/01 to 2019/10/04: English

Studies were screened using the inclusion and exclusion criteria



Excluded articles

The table below lists the articles excluded after full-text screening for this systematic review question. At least one reason for exclusion is provided for each article, which may not reflect all possible reasons. Information about articles excluded after title and abstract screening is available upon request.

Table 12. Articles excluded after full text screening with rationale for exclusion

	Citation	Rationale
1	[Unavailable]. Correction: The impact of dietary habits and metabolic risk factors on cardiovascular and diabetes mortality in countries of the Middle East and North Africa in 2010: a comparative risk assessment analysis. <i>BMJ Open</i> . 2019. 9:e006385corr1 https://www.ncbi.nlm.nih.gov/pubmed/31048450	Study design, Publication Status
2	[Unavailable]. Dietary alpha-Linolenic Acid, Marine omega-3 Fatty Acids, and Mortality in a Population With High Fish Consumption: Findings From the PREvencion con Dieta MEDiterranea (PREDIMED) Study. <i>J Am Heart Assoc</i> . 2016. 5:#pages# https://www.ncbi.nlm.nih.gov/pubmed/26873691	Study Design, Intervention/Exposure, Publication Status
3	[Unavailable]. Erratum for Juanola-Falgarona et al. Dietary intake of vitamin K is inversely associated with mortality risk. <i>J Nutr</i> . 2016. 146:653 https://www.ncbi.nlm.nih.gov/pubmed/26933059	Study Design, Intervention/Exposure, Publication Status
4	[Unavailable]. Vegetarian diets aid longevity, reduce risk of ACM. But results are more significant in men than women. Further research is needed to determine why. <i>Duke Med Health News</i> . 2013. 19:4-5 https://www.ncbi.nlm.nih.gov/pubmed/23984452	Study design, Publication Status
5	Abrahams, Z, McHiza, Z, Steyn, NP. Diet and mortality rates in Sub-Saharan Africa: stages in the nutrition transition. <i>BMC Public Health</i> . 2011. 11:801 https://www.ncbi.nlm.nih.gov/pubmed/21995618	Intervention/Exposure, Outcome
6	Abu-Saad, K, Novikov, I, Gimpelevitz, I, Benderly, M, Alpert, G, Goldbourt, U, Kalter-Leibovici, O. Micronutrient intake and adherence to DASH diet are associated with incident major adverse cardiovascular events and ACM in a bi-ethnic population. <i>European heart journal</i> . 2017. 38:1120â€” https://www.cochranelibrary.com/central/doi/10.1002/central/CN-01468739/full	Study design, Publication Status
7	Afshin, A, Micha, R, Khatibzadeh, S, Fahimi, S, Shi, P, Powles, J, Singh, G, Yakoob, MY, Abdollahi, M, Al-Hooti, S, Farzadfar, F, Houshfar-Rad, A, Hwalla, N, Koksai, E, Musaiger, A, Pekcan, G, Sibai, AM, Zaghloul, S, Danaei, G, Ezzati, M, Mozaffarian, D. The impact of dietary habits and metabolic risk factors on cardiovascular and diabetes mortality in countries of the Middle East and North Africa in 2010: a comparative risk assessment analysis. <i>BMJ Open</i> . 2015. 5:e006385 https://www.ncbi.nlm.nih.gov/pubmed/25995236	Outcome, Country
8	Agarwal, E, Ferguson, M, Banks, M, Vivanti, A, Batterham, M, Bauer, J, Capra, S, Isenring, E. Malnutrition, poor food intake, and adverse healthcare outcomes in non-critically ill obese acute care hospital patients. <i>Clin Nutr</i> . 2019. 38:759-766 https://www.ncbi.nlm.nih.gov/pubmed/29559233	Intervention/Exposure, Health Status

Data was extracted from each included study

- Study design, study or cohort name
- Country
- Sample size
- Participant characteristics
- Dietary pattern examined, dietary assessment methods
- Outcome assessment methods
- Analysis, confounders accounted for
- Results
- Funding source

Waijers et al, 2006¹²⁷ PCS, European Prospective Investigation into Cancer and Nutrition (EPIC)-Elderly project Netherlands Analytic N: 5427 Attrition: 15% Sex: 100% female Race/ethnicity: NR SES: Education: ~33.3% None or primary school, ~25.7% Technical school, ~29.7% Secondary school, ~10.3% University degree Alcohol intake: mean 7.3 g	Dietary pattern(s): Adherence to three dietary patterns identified using factor analysis (PCA) as follows: • 'Mediterranean-like' - High consumption of pasta and rice, sauces, fish, and vegetables in combination with vegetable oils, wine, and other cereals (potatoes, bread, and margarine, contributed negatively to this component) • 'Traditional Dutch dinner' - High consumption of meat, potatoes, vegetables, eggs, and alcoholic beverages. Low consumption of dairy products, sweets, and pastries. • 'Healthy Traditional' - High consumption of vegetables, fruit, dairy products, potatoes, and legumes, and also nonalcoholic beverages. Low consumption in intakes of butter and alcoholic beverages. Dietary assessment methods: 178-item validated semi quantitative FFQ at baseline, age ≥60 y (~58.7% age 60-64y, ~41.3% age 65-70y) Outcome assessment methods: Data on vital status, including emigration or death were obtained through the National Population Database.	Significant: 'Healthy Traditional' dietary pattern and ACM over ~8.2y f/u with T1, HR: 1, ref: • T3 HR: 1.25, 95% CI: 0.52, 0.95 Non-significant: 'Mediterranean-like' dietary pattern and ACM over ~8.2y f/u with T1, HR: 1, ref: • T2 HR: 0.91 NS • T3 HR: 0.84 NS 'Traditional Dutch Dinner' dietary pattern and ACM over ~8.2y f/u with T1, HR: 1, ref: • T2 HR: 1.00 NS • T3 HR: 1.25 NS 'Healthy Traditional' dietary pattern and ACM over ~8.2y f/u with T1, HR: 1, ref: • T2 HR: 0.81 NS	Key confounders accounted for: Sex: Design; Age; Race/ethnicity: Design; 100% Dutch; SES: Education; Alcohol: Part of dietary pattern; Physical activity; Anthropometry: BMI; waist-to-hip ratio; Smoking Other: Total energy intake; Diabetes Limitations: • Small number of total deaths in the study (n=277) • Food groups selected for analyses may not optimally represent dietary choices of Dutch persons	Higher adherence (T3 vs. T1) to the 'Healthy Traditional', with higher intake of vegetables, fruit, dairy products, potatoes, and legumes, and non-alcoholic beverages; lower intakes of butter and alcoholic beverages, dietary pattern was associated with significantly lower risk of ACM over ~8 years f/u. No significant associations were observed between adherence to the 'Mediterranean-like' and 'Traditional Dutch dinner' dietary patterns and ACM. Funding: Quality of Life and Management of Living resources Program of the European Commission
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A risk of bias tool was used to assess each included study

Risk of bias is the likelihood of a systematic error or deviation from the truth in results. Biases can lead to underestimation or overestimation of the true effect of an intervention/exposure on an outcome.

(Cochrane Handbook, 2019)

- Randomization
- Selection of participants
- Confounding
- Classification of interventions or exposures
- Deviations from intended interventions or exposures
- Missing data
- Outcome measurement
- Selection of the reported result

NESR used 3 study design-specific tools to assess risk of bias:

- Cochrane risk-of-bias tool for randomized trials (RoB 2.0)
- Risk of Bias in Non-randomized Studies-of-Interventions tool (ROBINS-I)
- Risk of Bias for Nutrition Observational Studies tool (RoB-NObs)

	Confounding	Selection of participants	Classification of exposures	Deviations from intended exposures	Missing data	Outcome measurement	Selection of the reported result
Chang-Claude et al, 2005 ¹³²	Moderate	Serious	Moderate	Serious	Moderate	Low	Moderate
Cheng et al, 2018 ²⁰	Moderate	Serious	Low	Serious	Moderate	Low	Moderate
Chrysohoou et al, 2016 ²¹	Critical	Critical	Critical	No information	Low	Moderate	Moderate
Cuenca-Garcia et al, 2014 ²²	Serious	Serious	Low	Serious	Moderate	Low	Moderate
Dai et al, 2016 ²³	Serious	Serious	Low	Serious	Moderate	Low	Moderate
Drake et al, 2013 ²⁴	Serious	Serious	Low	Serious	Moderate	Low	Moderate
Ford et al, 2014 ²⁵	Serious	Moderate	Low	Serious	Serious	Low	Moderate
Ford et al, 2012 ²⁶	Serious	Moderate	Low	Serious	Serious	Low	Moderate
Ford et al, 2011 ²⁷	Serious	Serious	Low	Serious	Moderate	Low	Moderate
Fresan et al, 2019 ²⁸	Moderate	Serious	Low	Serious	Serious	Low	Moderate
George et al, 2014 ²⁹	Moderate	Serious	Low	Moderate	Moderate	Low	Moderate
Granic et al, 2013 ¹¹⁶	Serious	Serious	Moderate	Moderate	Serious	Low	Moderate
Hamer et al, 2010 ¹¹⁷	Serious	Serious	Low	Moderate	Moderate	Low	Moderate
Harmon et al, 2015 ³⁰	Moderate	Serious	Low	Serious	Moderate	Low	Moderate
Hashemian et al, 2019 ³¹	Serious	Serious	Low	Serious	Moderate	Low	Moderate
Haveman-Nies et al, 2002 ³²	Serious	Moderate	Moderate	Moderate	Serious	Low	Moderate
Heidemann et al, 2008 ¹¹⁸	Serious	Serious	Low	Low	Moderate	Low	Moderate
Heroux et al, 2010 ¹³³	Serious	Serious	Moderate	Serious	Critical	Low	Moderate
Hodge et al, 2011 ³⁴	Serious	Serious	Low	Serious	Moderate	Low	Moderate
Hodge et al, 2018 ³³	Serious	Moderate	Low	Serious	Moderate	Low	Moderate

The evidence from all included studies was synthesized



The evidence from multiple studies was described, compared and contrasted, and combined.

- Are there overarching themes or key concepts from the findings?
- What are the similarities and differences between studies?
- Are certain factors impacting the relationships being examined?

INDEX/ SCORE - Country specific	Japanese Dietary Index	Japanese Food Score	Programme National Nutrition Sante Guideline Score - France (PNNS-GS)	Diet Quality Index - Sweden (DQI-SNR)	Diet Quality Index - Korea (DQI-K)	Healthy Nordic Food Index (HNFI)	Traditional Sami Diet Score
Total Score	0-9	0-7	0-15	0-6	0-9	0-6	0-8
Vegetables	Seaweeds, Pickles, Green, Yellow Vegetables (green vegetables, carrot, pumpkin, tomato) (+)	Vegetables (spinach or garland chrysanthemum, carrots or pumpkin, tomatoes, cabbage or head lettuce and Chinese cabbage) (+) Japanese Pickles (+) Fungi (+) Seaweeds (+)	Vegetables and Fruit (+)	Vegetables and Fruit (+)	Vegetables (+)	Cabbage (+) Root Vegetables (+)	
Legumes		Beans and Bean Products (boiled beans and tofu) (+)	Included in grains				
Fruit		Fruit (+)	Included in vegetables				
Nuts							
Whole Grains							
Grains, unspecific	Rice (+)		Bread, cereals, potatoes, and legumes (+m)				
Refined Grains							
Fish/Seafood	Fish (rawfish, fish boiled with soy, roast fish, boiled fish paste, dried fish) (+)	Fish (fresh) (+)	Seafood (+)				
Meat	Beef and Pork (beef, pork, ham, sausage) (+)		Meat and Poultry, Seafood, and Eggs (+m)				
Dairy			Milk and Dairy Products (+m)				
Sugar Sweetened Beverages, Sweets			Sweetened Foods (-) Soda (drink water) (-)				
Fat			Vegetable Fat (+) Added fat (-)				
Carbohydrates							
Protein							
Alcohol			Alcohol (+m)				

Evidence synthesis

Summary of results

Dietary patterns were assessed using a variety of different methods. The following sections provide a description of results according to the approach used to examine dietary patterns.

Randomized controlled trial

One article randomized participants to consume two different Mediterranean diets or a control low-fat diet.¹ This study was from a multicenter, trial in Spain that assigned participants at high-risk for CVD to consume a Mediterranean diet with extra-virgin olive oil (EVOO), a Mediterranean diet with mixed nuts, or a control diet with advice to reduce dietary fat (see Table 3). Consumption of the Mediterranean diets with EVOO or mixed-nuts were significantly associated with reduced all-cause mortality risk after (median) 4.8y. Results were similar in sub-analyses removing participants subject to protocol deviations and randomization issues.

Observational studies

Index/score analysis

The majority of included studies examining the relationship between dietary patterns and all-cause mortality came from prospective cohort designs that used index or score analysis (see Table 4). Among these studies, nearly 80 different indices or scores were used to examine dietary patterns that included 30 different "Mediterranean" indices, e.g., the "Mediterranean Diet Score" or "Alternate Mediterranean Diet Score", 7 different "Healthy Eating Index (HEI)" or "Dietary Guidelines for Americans" indices e.g., HEI-2010; 1 Dietary Approaches to Stop Hypertension (DASH) score, 16 different country-specific indices e.g., Dutch Healthy Diet Index 2015, and, 24 other indices or scales, e.g., "Recommended Food Score". For more information about the components and scoring procedures within each of these indices/scores (Table 1).

Despite variability between the indices/scores used, the findings across these studies were consistent in the majority of studies that used index or score analysis, suggesting that adherence to dietary patterns generally regarded as "healthier" were associated with reduced risk of all-cause mortality. Subsets of these articles reported null findings between the dietary patterns examined

A conclusion statement was developed to answer the systematic review question

What is the relationship between dietary patterns consumed and all-cause mortality?

Strong evidence demonstrates that dietary patterns in adults and older adults characterized by vegetables, fruits, legumes, nuts, whole grains, unsaturated vegetable oils, and fish, lean meat or poultry when meat was included, are associated with decreased risk of all-cause mortality. These patterns were also relatively low in red and processed meat, high-fat dairy, and refined carbohydrates or sweets. Some of these dietary patterns also included alcoholic beverages in moderation. (Grade: Strong)

The strength of the evidence underlying each conclusion statement was graded

Strong evidence demonstrates that dietary patterns in adults and older adults characterized by vegetables, fruits, legumes, nuts, whole grains, unsaturated vegetable oils, and fish, lean meat or poultry when meat was included, are associated with decreased risk of all-cause mortality. These patterns were also relatively low in red and processed meat, high-fat dairy, and refined carbohydrates or sweets. Some of these dietary patterns also included alcoholic beverages in moderation. (Grade: Strong)

Risk of bias: Most studies were well designed and conducted using rigorous methods, and accounted for key confounders

Consistency: Results across a variety of different methods used to examine or derive dietary patterns were remarkably consistent, the majority of studies found statistically significant relationships between dietary patterns consumed and all-cause mortality risk

Directness: The populations, intervention, comparators, and outcomes of interest in the included studies are directly related to the systematic review question.

Precision: Effects were relatively consistent in magnitude and the width of confidence intervals between studies was relatively narrow

Generalizability: The study participants, interventions and/or exposures, comparators, and outcomes examined in the body of evidence are applicable to the United States population

***Study design:** 141 articles, including 1 RCT and 140 prospective cohort studies

Recommendations were made for designing, implementing, and reporting future research

1. Assess diet at more than one time-point, preferably over the entire course of follow-up
2. Examine the relationship between dietary patterns earlier in life and all-cause mortality
3. Further differentiate specific foods and food groups, for example, between processed meats and red meats as opposed to one category of “meat”
4. Provide sufficient information and repeated measures on the quantity of foods and beverages consumed
5. Identify inadequate or excessive intakes of specific foods and beverages to better disentangle the contribution of individual dietary components on any given dietary pattern
6. Consider effect modification or mediating factors such as weight status/BMI, physical activity, emerging biomarkers, health disparities, household food insecurity status
7. Include diverse populations with varying race/ethnicity, socioeconomic background, and chronic disease status

The Committee's NESR systematic reviews were peer-reviewed by Federal scientists

- New to the 2020 process, and based on recommendations from the National Academies
- Coordinated by USDA's Agricultural Research Service (ARS), and involved Federal scientists from USDA, HHS (NIH, CDC, and FDA), Department of Defense, and the Department of Veterans Affairs
- NESR staff addressed editorial comments, substantive comments were reviewed and discussed by Subcommittees, and revisions were made to the systematic review, as needed

Completed systematic reviews are posted online to ensure transparency and accessibility



The 2020 Committee conducted 33 systematic reviews, and used 16 existing NESR reviews

All systematic reviews and more details about the methodology are available at:
<https://nesr.usda.gov/>

Designing, Implementing and Presenting Observational Research: Lessons Learned from the 2020 Dietary Guidelines Advisory Committee



Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	None
Scientific Advisory Board/Consultant/Board of Directors	None
Speakers Bureau	None
Stock Shareholder	None
Employee	U.S. Department of Agriculture
Other	None

Research recommendations for designing, implementing, & presenting observational research are available in all NESR systematic reviews



Individual systematic reviews describe recommendations relevant to specific research questions and are available at: <https://nesr.usda.gov/>



The Scientific Report of the 2020 Dietary Guidelines Advisory Committee describes overarching and topic specific recommendations and is available at: <https://www.dietaryguidelines.gov/2020-advisory-committee-report>

“

The DGA require multiple sources of evidence to address the breadth of its scope. Data will need to come from varying study designs, such as randomized trials and observational studies.

These aggregate data, analyzed with the most current methodology, provide complementary evidence to answer different inferential questions and inform various parts of the evidence base. Properly evaluating and calibrating results from a variety of data sources and methodological approaches is critical to understanding and interpreting the body of evidence to arrive at appropriate conclusions, as all study designs have innate limitations and can be susceptible to different types of bias.

”

Observational studies provide critical evidence on diet and health

Rigorously conducted observational studies provide evidence on:

- Habitual diet
- Difficult to study exposures (e.g., dietary patterns)
- Large numbers of people
- Underrepresented or vulnerable populations
- Distal endpoints (e.g., growth, chronic disease, mortality)
- Factors that may influence the diet/health relationship (e.g., weight status, physical activity, socioeconomic status)

Summary of observational research enhancements to inform future dietary guidance

- ✓ Select study participants that reflect the diversity of the U.S. population
→ Describe the study population in detail
- ✓ Classify exposure groups using standard criteria or definitions
- ✓ Assess dietary intake at multiple time points across follow-up
→ Examine dietary intake at critical exposure periods across the lifespan
- ✓ Define foods, food groups, or other food components in as much detail as possible
- ✓ Improve the comparability of outcome measures
- ✓ Consider confounders, effect modifiers, and mediators that could impact results

Select study participants that reflect the diversity of the U.S. population

Describe and evaluate the impact of study participant characteristics

- Age and life stage
- Culture, race, and ethnicity
- Socioeconomic status
 - Food security
 - Food access



What is the relationship between dietary patterns before and during pregnancy and risk of gestational diabetes mellitus?

Limited but consistent evidence suggests that certain dietary patterns before pregnancy are associated with a reduced risk of gestational diabetes mellitus. These protective dietary patterns are: higher in vegetables, fruits, whole grains, nuts, legumes, and fish, and lower in red and processed meats. Most of the research was conducted in healthy, Caucasian women with access to health care.

Describe the study methods in detail

Report the number of participants at each stage to aid interpretation of study results, including:

- Response rate
- Exclusion criteria
- Enrollee vs. non-enrollee differences
- Reasons for missing data
- Attrition measure
- Differences between those lost to follow-up and those who remained



Classify exposure groups using standard criteria or definitions

Classify dietary habits and behaviors based upon intake over the study timeframe, for example:



- Among infants, adopt feeding categorization which reflects dose, frequency, intensity and/or timing of human milk, infant formula, and mixed feeding
- Lack of a standard definition for “eating occasion” impedes classification of groups by the number or timing of eating occasions reflecting customary meal and snack patterns

Assess dietary intake at multiple time points across follow-up

- Few studies report multiple measures of dietary intake
 - Recommend dietary exposures be assessed regularly over the follow-up period
 - Cohorts with systematically collected dietary data over the lifespan of the cohort are needed
- Improve and validate dietary assessment tools to accurately assess diet over the life course



Examine dietary intake at critical exposure periods across the lifespan

- Design studies that examine diet during specific phases of life
 - Examine how preconception diet, BMI, and metabolic health, are related to maternal and child outcomes
 - Investigate patterns and proportions of human milk feeding and health outcomes in mother and offspring



Define foods, food groups, or other food components in as much detail as possible

- Avoid unclear and broad terms such as “meats”, “dairy”, “soda”, “juice”, “vegetarian pattern”
 - Report more clear distinctions on types and sub-types
 - Provide distinctions on amounts and thresholds
 - Provide adequate information on the source
- Fully describe total energy intake assessment
- Valid and consistent methods are needed to assess water and alcoholic beverages



Improve the comparability of outcome measures



Use valid, reliable, standardized, age-appropriate assessment methods for children, particularly for developmental domains

- Describe method, timing, setting, and training of assessors
- Avoid relying solely on parent-report



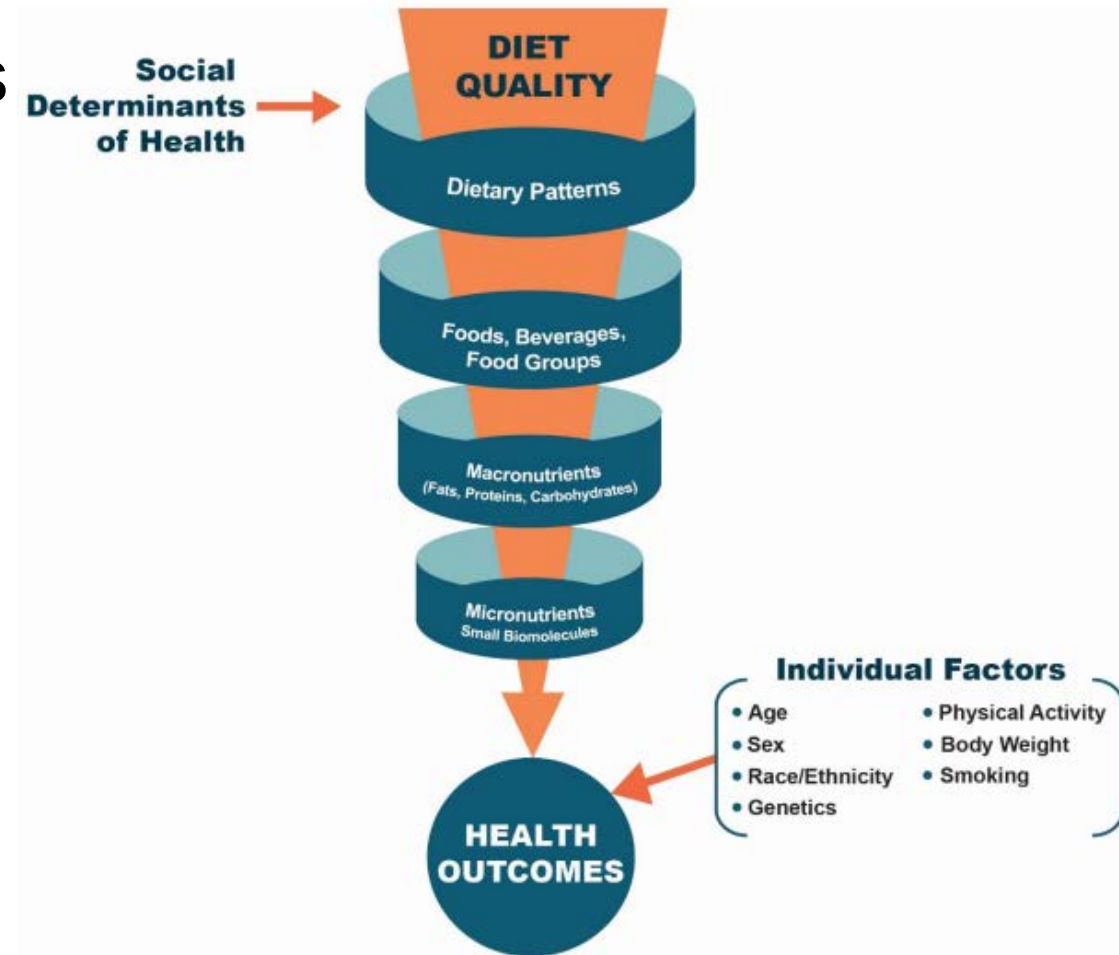
Use standardized measures and cut-points
e.g., standardized birth size



Report risk of stroke, separately from risk of coronary heart disease (CHD) and CHD mortality

Consider confounders, effect modifiers, and mediators that could impact results

- Examine diet and health relationships in the context of effect modifiers and mediators
 - Provide insight into subgroups for specific guidance
- Report key confounders considered
 - Rationale for selecting variables controlled
 - Provide sensitivity and sub-group analysis



Acknowledgements

2020 Dietary Guidelines Advisory Committee Membership

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Considerations for Clinical Trial Research Methodology & Potential to Inform Dietary Guidance

Jamy Ard, MD



Disclosures

AFFILIATION/FINANCIAL INTERESTS (prior 12 months)	ENTITIES
Grants/Research Support	Boeringher-Ingelheim, Nestle Health Sciences, Eli Lilly, UnitedHealth Group R&D
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Speakers Bureau	
Stock Shareholder	
Employee	Wake Forest School of Medicine
Other	

“

The Dietary Guidelines Advisory Committee (DGAC) has the “time-limited task of examining the evidence on specific nutrition and public health topics” to provide “independent, science-based advice to the Federal government” to support the development of the *Dietary Guidelines for Americans* (DGA).

”

3 approaches to building the “Report”



Data Analysis



**Food Pattern
Modeling**



**NESR
Systematic Reviews**

Sets the
focus

Sets the criteria by
which studies will be
included/excluded

How bias
will be
assessed

(Research question + analytic framework + quality
assessment framework)

Individuals conducting the review =

Systematic Review

DGAC members set the
AF and assess bias.
Conclusions are the
interpretation of the
members.

“

Why wasn't my paper included?

Things to know if you want your research to influence the DGAC report

”

1

**The Report is
not about
disease
treatment**

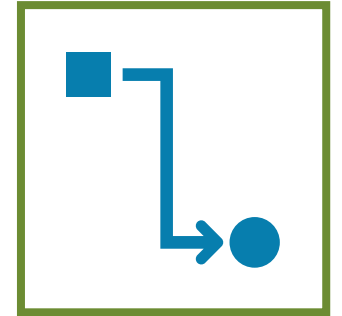
Focus is PREVENTION

Examples:

- Prevention of obesity, excess weight gain
- Cardiovascular disease, CVD mortality
- Type 2 diabetes
- Cancer

Methodology implications

- Including populations without the condition
 - Those with pre-diabetes and type 2 diabetes
 - Individuals at high risk of CVD but no known CVD
- Interventions that prescribe treatment not included
 - Most commonly excludes weight reduction studies - prescribed calorie restriction



2

**The dietary
pattern was not
well-defined
(or at all)**

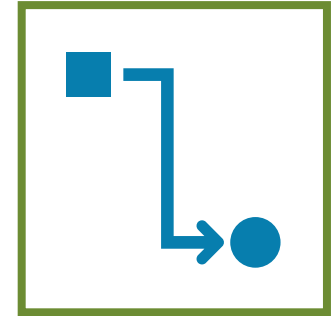
**DGA have shifted to DIETARY
PATTERN perspective over
the past few cycles**

Examples:

- DASH
- Healthy U.S.-Style
- Vegetarian
- Mediterranean

Methodology implications

- There has to be sufficient detail reported to determine what the dietary pattern is/what the individuals consumed
- Related: the period of exposure or estimation of habitual intake should be derived from more than one time point



3

**The definitions
are consistently
inconsistent**

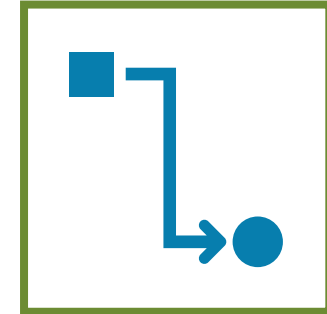
**Nutrition research is rife with
constructs that are inconsistently
defined across studies**

- Limits ability to compare studies
- Limits ability to offer clear recommendations

Methodology implications

For the broader nutrition community

- Agreement on meanings/nomenclature
 - Example: what does “low carb” mean?
 - Example: eating frequency - how is an eating episode defined?
- Adoption of standardized definitions to improve comparability across studies



Examples from the Report

Relationship between frequency of eating and growth, size, body composition, and risk of overweight and obesity
(Insufficient evidence)

6 studies total

- Definition of eating occasions varied in EVERY study
- Beverages were inconsistently accounted for within eating occasions
- Eating frequency only done at baseline

Examples from the Report

Dietary intakes based on macronutrient distribution outside of the AMDR

- Several studies qualitatively identified a dietary intake pattern as low carb or high protein, but the intake was within the AMDR for the given macronutrient (45-65% CHO, 10-35% PRO)
 - In some instances, the differences between groups was relatively small (e.g., 45.3% vs 43.8% CHO)
- Inability to isolate the effects of the macronutrient distribution from the overall dietary pattern or energy intake

For more details and considerations

See Part E. Future Directions in the 2020 DGAC Report

Recommended list of considerations for researchers

- For example:

- Include diverse populations
- Identify impact of social determinants, effect modifications

Specific recommendations for each topic area covered by DGAC



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Discussion

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